IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF
PATENT APPEALS AND INTERFERENCES

In re Application of:	John A. Kink *et al.*		
Serial No.:	09/832,233	Art Unit:	1617
Filed:	04/10/2001	Examiner:	Wang, S.
Entitled:	**Prevention and Treatment of Necrotizing Enterocolitits**		

REPLY TO EXAMINER'S ANSWER TRANSMITTAL

Mailstop - Appeals
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

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Dated: February 8, 2007

By: _____
Traci E. Light

Board Of Patent & Trademark Appeals:

On December 8, 2006, the Examiner mailed an Answer to Applicant's Appeal Brief wherein new points of argument are made. Pursuant to 37 CFR 1.193 (b)(1), Applicant hereby provide a Reply Brief wherein the new points of argument are addressed.

Since the Reply Brief is filed within two months of the date of mailing of the Answer, the Reply Brief is timely. The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. **08-1290**. **An originally executed duplicate of this transmittal is enclosed for this purpose**.

Respectfully submitted

MEDLEN & CARROLL, LLP

Dated: 2/8/2007

By: _____
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PATENT
Attorney Docket No. **OPHD-06331**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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In re Application of:	John A. Kirk *et al.*		
Serial No.:	09/832,233	Art Unit:	1617
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Entitled:	**Prevention and Treatment of Necrotizing Enterocolitits**		

REPLY BRIEF TO EXAMINER'S ANSWER MAILED DECEMBER 8, 2006

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Commissioner for Patents
P.O. Box 1450
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Dated: February 8, 2007

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Examiner Wang:

On December 8, 2006 the Examiner mailed a substitute Answer to Applicant's Appeal Brief wherein new points of argument are made. Pursuant to 37 CFR 1.193 (b)(1), Applicants hereby provide a substitute Reply Brief wherein the new points of argument are addressed.

Since the Reply Brief is filed within two months of the date of mailing of the Answer, the Reply Brief is timely. Nonetheless if there are any fees required and/or any required Petition for Extension of Time for filing this Reply Brief, they are dealt with in the accompanying **TRANSMITTAL OF REPLY BRIEF**.

ARGUMENT

A. The Examiner Mischaracterizes Eibl II

The Examiner has set forth a new point of argument. The Examiner asserts, for the first time, that Eibl II teaches that "endotoxemia [] has been associated to the pathogenesis of NEC." *Examiner's Answer, page 15, lines 10-11.* Applicants cannot agree. Eibl II does not mention that endotoxemia is associated with NEC. The link of endotoxemia to NEC is not completed by the teachings of Eibl II.

The passage in Eibl II that the Examiner is referring to states:

> Endotoxins are known to induce IL-6 synthesis, and serum levels of IL-6 are increased in conditions associated with endotoxemia such as thermal injury. The deleterious effects of bacterial toxins are associated with the exaggerated and self-amplifying release of these compounds that cause inflammation, often with lethal results. The lethality of gram-negative bacteremia or endotoxemia has been prevented by the administration of specific, anti-TNF antibodies.

Ebil II col 2 ln 2 - 10. Bacteremia occurs when bacteria enter the bloodstream. Endotoxemia is a condition where endotoxin (toxic substances associated with certain bacteria) access the blood stream. These statements suggest anti-TNF antibodies can be useful for the treatment of bacteremia or endotoxemia. However, Eibl II does not provide the motivational nexus for an anti-TNF therapy for NEC. Furthermore, when the Examiner states that:

> Eibl[] II further establishes expectation of success by stating "endotoxin challenge and administration of TNF has induced bowel necrosis in an experimental animal model of NEC".

Examiner's Answer pg 13, nothing could be further from the truth. To establish an expectation of success, Ebil II must provide an explicit teaching that anti-TNF-α antibody prevents TNF-α induced (alone) bowel necrosis in an experimental animal model of NEC, not complicated with a

combination with an endotoxin.[1] The fact that Eibl II mentions that anti-TNF antibodies prevent endotoxemia lethality is irrelevant to the presently claimed embodiment.

What Eibl I and II do teach is the use of IgA/IgG preparations, which are simply made by fractionating human serum, *i.e.* without any use of antigen. Tables 1 and 2 in Eibl I show that the human serum fraction has some inherent reactivity with pathogens. There is no readily apparent evidence or data (and the Examiner points to none) supporting the notion that the IgA/IgG preparations have antibodies to TNF. Indeed, the authors of the reference speculate that the mechanism of action is through pathogen binding. Thus, at best, the antibody preparation of these references is directed to pathogen antigens. By contrast, the present claims say nothing about anti-pathogen antibodies.

In the original Appeal Brief the Applicants presented a persuasive argument that Eibl II teaches away from the Applicants' claimed embodiment. Instead of factually rebutting this argument, the Examiner has attacked the Applicants' understanding of patent law:

> In response, Examiner states that Eibl at no place provides any teachings that amount to a direct teaching away from the instant claims. Appellant appear to misinterpret what it means to "teach away" from a patented invention.

Examiner's Answer, pg. 14. The Examiner then cites to a rather inarticulate (and seldom used) quotation from *Gurely et al.* in an attempt to support the above accusation. The Applicants have noticed that the Examiner compares the teachings of Ebil II with the teachings of Le et al. in an attempt to show why the Applicants misunderstand "teaching away":

> Here, the mere fact that there is an alternative means of reducing TNF activity in a TNF-mediated disease, as shown by Eibl II, does not [...] preclude the use of the anti-TNF antibodies of Le for treating NEC.

and,

[1] *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988).

> In fact the portions of Eibl II patent that Applicant characterizes as a "teaching away," col 2, lines 24-27, does not discourage one of ordinary skill in the art to employ the anti-TNF antibodies of Le for treating NEC.

Examiner's Answer pg. 14. The Board is reminded that the Applicants state that:

> Ebil II also teaches away from the Applicants' claimed embodiment ...

Applicants' Appeal Brief, pg. 12 ln 12. Consequently, what effect Ebil II has on one having ordinary skill in the art to use the teachings of Le et al. is completely irrelevant. The Board is requested to consider a more accepted definition of "teaching away" that the Applicants believe is more appropriate for this decision[2]:

> A reference may be said to teach away when a person of ordinary skill, upon [examining] (sic) the reference ... would be led in a direction divergent from the path that was taken by the applicant.

Para-Ordnance Manufacturing v. SGS Importers International, 37 USPQ2d 1237,1241 (Fed. Cir. 1995) (quoting *In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994)). The Applicants' believe that the "teaching away" argument is proper.

B. The Examiner Overstates The Relationship Between TNF & NEC

The Examiner concludes that "The role of TNF in the development of neonate NEC has been well established in the art" by suggesting that Eibl II teaches "a correlation between levels of TNF and the pathogenesis of neonatal NEC (see col 1,lines 60-66)" and that Muguruma teaches the role of TNF in the pathogenesis of NEC (Examiner's Answer pg 5). The Applicants submit that the Examiner has improperly applied teachings of Eibl II regarding meningococcemia or septic shock to NEC. In particular, the Examiner cites:

> Furthermore, high serum levels of TNF-α correlate with the mortality of patients with meningococcemia or septic shock. High levels of TNF-α have also been found in

[2] This decision, in fact, quotes from *In re Gurely*.

> neonates with necrotizing enterocolitis, suggesting that TNF-α may be involved in the pathogenesis of this disease.

Eibl II, col 1 ln 60-64 [emphasis added]. The Board should realize that Eibl II refers to a TNF-α correlation only with regards to meningococcemia or septic shock. Eibl II did not teach, nor intended to teach, that TNF-α was correlated to NEC. In fact, Eibl II specifically uses the phrase "may be involved" clearly indicating that Eibl II is speculating on this point. The Examiner is not permitted to conclude otherwise. Further, the Examiner actually admits that Eibl II teaches "TNF may be involved in the pathogenesis of NEC." *Examiner's Answer, pg 13 ln 22-23* [emphasis added]. Wolf et al. provides further evidence that any proposed link between NEC and TNF-α is uncertain:

> ... [a]n exaggerated release of mediators of inflammation has also been implicated in the pathogenesis. In infants with NEC, plasma levels of inflammatory cytokines like platelet activating factor (PAF) and tumor necrosis factor (TNF) are elevated.

Wolf et al., pg 38 lhc last para, first sentence [emphasis added]. In analyzing just these two references alone, the Board must realize already that the Examiner is making conclusions without proper basis.

In regards to Muguruma et al., the Examiner has clearly not read the complete article. First, Muguruma et al. administers a combination of TNF-α AND lipopolysaccaride. More importantly, however, the development of NEC was not observed:

> Upon gross examination, all of the vehicle treated animals showed severe hemorrhage (Figure 4), but, when examined microscopically, necrotizing enterocolitis was not present.

Muguruma et al., pg 575 lhc, last sentence – pg 576 rhc, first sentence. Muguruma et al. never shows the development of NEC and never administers TNF-α alone. Consequently, the

Examiner has erred by citing Muguruma et al. to show that TNF-α has a well established link to NEC.

These misunderstandings regarding the teachings of Eibl II, Wolf et al., and Muguruma et al. clearly establish that any proposed link between TNF-α and NEC is not well established in the art. The Applicants reassert the 'obvious to try' rebuttal (based upon *In re O'Farrell*) in the original Appeal Brief to which the Examiner has attempted to explain away. The Examiner criticizes this argument, not with facts, but by creating a new legal construct not examined in *In re O'Farrell*:

> ... analogous to the In re O'Farrell, the correct question here is: when is an invention that is obvious to try nevertheless obvious.

Examiner's Answer pg 10. The Applicants disagree and remind the Board that *In re O'Farrell* stands for the proposition that the question of reasonable success is whether the art indicates Applicant's approach will succeed:

> The expectation of success must come from the prior art and explicitly predict that the process recited in the claims would work.

In re O'Farrell, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). The Examiner admits that *In re O'Farrell* establishes two kinds of error: i) those predicated upon situations where a cited reference requires one having ordinary skill in the art to 'vary all parameters or try each of numerous possible choices'; and ii) those predicated upon situations where a cited reference explores a new technology or general approach that seemed promising but only gave general guidance. *Examiner's Answer pg 10 last paragraph – pg 11 first paragraph.*

The Examiner then incorrectly attempts to extract Le, Ebil I, Ebil II, Wolf et al., and Muguruma et al. from the 'obvious to try' definition:

> However, neither of these situations applies here. Using anti-TNF antibodies for TNF-mediated diseases have been well described in the art as evidence by Le's Patent.

> Further, the role of TNF in pathogenesis of NEC has been well described as evidenced in Eibl, Wolf and Muguruma. There exists no varying of "all parameters' or "trying numerous possible choices among many parameters." All that is required here is mere application of Le's anti-TNF antibodies to another TNF mediated inflammatory disease such as NEC.

Examiner's Answer pg 11 second paragraph. The Board is reminded that Le et al. does not teach anti-TNF antibodies that meet the Applicants' claimed embodiment. Le et al. teaches recombinant humanized chimeric antibodies NOT polyclonal avian antibodies. As the Applicants discuss below, Le et al. discourages the use of any antibody except a chimeric antibody (i.e., at least partly human).

If anything, looking at these references collectively, one skilled the art would conclude that they teach that TNF does not "play a primary role" in NEC. Thus, the definitive link of TNF to NEC is not completed by the teachings Eibl, Wolf, and Muguruma.

It is respectfully submitted that the Examiner - only after reading the Applicants' disclosure - can now go back and try to connect these unrelated statements (i.e., hindsight reconstruction as to what the Eibl II teaches one skilled in the art).

C. Le et al. Provides No Motivation For Any Combination

The Examiner apparently takes the position that Le et al. provides motivation to use anti-TNF antibodies for any and all TNF-associated disease. In particular, the Examiner states that:

> ... Le clearly teaches anti-TNF antibodies for use in TNF related pathologies.

Examiner's Answer, pg. 9. ln 2-3. The Applicants assert that the Examiner is not properly interpreting Le et al. against the claimed embodiment. The Applicants point out that the claims are directed to an embodiment having the elements: i) polyclonal avian antibodies; and ii) administration into the lumen of the intestine (i.e., for example, oral administration). The Examiner has ignored these claim limitations in framing this rejection.

First, Le et al. does not teach "anti-TNF antibodies" of a generic nature. In fact, the Applicants draw the Board's attention to Le's title: "Methods Of Treating TNF-a-Mediated Crohn's Disease Using Chimeric Anti-TNF Antibodies" [emphasis added]. Chimeric antibodies are hybrids of two different species. In the case of Le et al., these chimeric antibodies consist of a hybrid of mouse and human. Consequently, Le et al. teaches humanized antibodies which Le et al. goes to great lengths to defend:

> Murine MAbs are undesirable for human therapeutic use due to a short free circulating serum half-life and the stimulation of a human anti-murine antibody (HAMA) response. A murine-human chimeric anti-human TNFα MAb was developed in the present invention with high affinity, epitope specificity and the ability to neutralize the cytotoxic effects of human TNF. Chimeric A2 anti-TNF consists of the antigen binding variable region of the high affinity neutralizing mouse anti-human TNF IgG1 antibody, designated A2, and the constant regions of a human IgG1, kappa immunoglobulin. The human IgG1 Fc region is expected to: improve allogeneic antibody effector function; increase the circulating serum half-life; and decrease the immunogenicity of the antibody. A similar murine-human chimeric antibody (chimeric 17-1A) has been shown in clinical studies to have a 6-fold longer in vivo circulation time and to be significantly less immunogenic than its corresponding murine MAb counterpart (LoBuglio et al., *Proc Natl Acad Sci USA* 86: 4220-4224, 1988).

Le et al., col 20 ln 17-35.

Second, Le et al. teaches away from enteral antibody administration, such as oral or administration to the lumen of the intestine:

> Because proteins are subject to being digested when administered orally, parenteral administration, i.e., intravenous, subcutaneous, intramuscular, would ordinarily be used to optimize absorption.

Le et al., col 35 ln 20-24. Despite these clear deficiencies, the Examiner argues that Le et al. provides proper motivation for a combination with the other cited references:

> [Le et al.] ... provides that such art ... are used to successfully treat various acute or chronic diseases with TNF-related pathologies ... Le explicitly exemplifies that use of anti-TNF for treatment of Crohn's disease and suggests expectation of success for treatment of TNF related pathologies ...

Examiner's Answer pg 12 last paragraph. The Applicants disagree and point to the following (and apparently overlooked) admission within Le et al. regarding the dangers of non-human antibody administration[3]:

> To date, experience with anti-TNF murine mAb therapy in humans has been limited, In a phase I study, fourteen patients with severe septic shock were administered a murine anti-TNF mAb in a single dose from 0.4-10 mg/kg (Exly, A. R. et al., *Lancet* 335: 1275-1277 (1990)). However, seven of the fourteen patients developed a human anti-murine antibody response to the treatment, which treatment suffers from the known problems due to immunogenicity from the use of murine heavy and light chain portions of the antibody. Such immunogenicity causes decreased effectiveness of continued administration and can render treatment ineffective, in patients undergoing diagnostic or therapeutic administration of murine anti-TNF antibodies.

Le et al. col 3 ln 27-40 [emphasis added]. Consequently, the Applicants disagree with the Examiner's following conclusion:

> Le, provide[s] direct teachings about the nature of anti-TNF antibodies ... and are used to successfully treat various acute or chronic diseases with TNF-related pathologies ...

Examiner's Action pg. 12. Again, the Examiner has overlooked the fact that Le et al. insists that anti-TNF antibodies must be chimeric (i.e., at least partly human) in nature to be clinically effective. Le et al. does not demonstrate the successful treatment of any disease using either non-chimeric monoclonal or non-chimeric polyclonal anti-TNF antibodies. Further, Le et al. does not provide any teachings showing that anti-TNF antibodies can successfully treat any disease having a TNF-related pathology.

Looking at the text of Le et al., the Examiner could argue (at most) that Le et al. provides motivation to use anti-TNF antibodies for treating, hepatitis, lupus, AIDS, cancer, and multiple sclerosis. These are all indications provided in Le et al. (with no data). Is the Examiner suggesting such a teaching in Le et al. means that anti-TNF antibodies could actually cure all

[3] Again, the Examiner is not placing the teachings of the cited art against the Applicant's claimed embodiment.

these diseases? Col. 33, line 56-Col 35, line 24. Using the Examiner logic, Le et al. motivates and teaches success for the use of anti-TNF antibodies to cure most all diseases known to man. Without data, the treatment of cancer has long been considered by the USPTO to be an incredible claim. It seems to be an extreme position to maintain that Le provides sufficient expectation of success for the treatment NEC when there is no data in Le confirming such an indication. The Examiner instead relies on the fact that anti-TNF worked for some other indications and the statement that "obviousness does not require absolute predictability of success." (Examiner's Answer page 12, lines 5-6).

The Board is reminded of the many cases that say the chemical and biological arts are inherently unpredictable. The Board is also asked to consider whether those skilled in the art at the FDA would take such an extreme position. For example, it is extremely unlikely the FDA would approve a phase 2 Investigational New Drug Application (IND) using anti-TNF antibodies for the treatment of NEC based on Le without animal data indicating that anti-TNF antibodies may be effective in treating the NEC.[4] The Examiner is merely disregarding that one skilled in the art would consider reasonable.

D. Williams et al. Cannot Be Combined With Le et al.

The above argument provides clear evidence that Le et al. does not provide any teachings suggesting that: i) a non-humanized polyclonal antibody should be used; and ii) administration of

[4] 21 CFR312.22 FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phase 2 and 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety. . . .FDA's review of Phases 2 and 3 submissions will also include an assessment of the scientific quality of the clinical investigations and the likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval.
21 CFR312.23. IND content and format. Section (a)(8)(i) Pharmacology and drug disposition. A section describing the **pharmacological effects and mechanism(s) of action of the drug in animals**, and information on the absorption, distribution, metabolism, and excretion of the drug, if known.

antibodies to the lumen of the intestines (i.e., for example, oral) should be used. Consequently, the Applicants do not agree with the Examiner's combination of Le et al. with Williams et al.

The Board is reminded that the Federal Circuit has held that the Examiner cannot create their own interpretation regarding the intended use of a cited reference in an attempt to support an obviousness rejection:

> In a proper obviousness determination, '[w]hether the changes from the prior art are 'minor', . . . the changes must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the patentee's . . . device.' Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 935, 15 USPQ2d 1321,1324 (Fed. Cir.), cert. denied, 498 U.S. 920, 111 S.Ct. 296, 112 L.Ed.2d 250 (1990). This includes what could be characterized as simple changes, as in In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (Although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art fairly suggested the desirability of turning the device upside down.).

In re Chu, 66 F.3d 292, 298, 36 USPQ2d 1089 (Fed.Cir. 1995). The Board should realize that without a teaching within Le et al. suggesting that a non-chimeric polyclonal antibody should be orally administered to a human, there is no basis for a Le et al./Williams et al. combination. The Examiner has essentially proposed a new, and unintended, use for Le et al. by "turning Le et al. upside-down" (i.e., by asserting that it contains teachings that it does not) in an attempt to justify this combination.

E. The Applicant Teaches "Direct Neutralization"

In the original Appeal Brief, the Applicants properly argued that Eibl II did not teach any antibodies that were specific against TNF-α (i.e., an anti-TNF antibody). The Examiner has responded by stating:

> Appellant also argues that Eibl II teaches that NEC immunotherapy does not involve direct neutralization by specific antibodies such as anti-TNF antibody. (see Brief at page 10, 3rd para). Aside from the fact that is not clear what is meant by the phrase "direct neutralization," because neither the specification nor the art teach such activities for an antibodies ...

Examiner's Answer, pg 11 last paragraph. The Applicants disagree and direct the Board to Example 3 entitled "Anti-TNF Cell Neutralization Assay" (See, Applicant's Specification, pg 16 ln 24). The first & last sentences of this example reads:

> This example demonstrates the neutralization capabilities of the anti-TNF IgY antibodies in an *in vitro* cell based bioassay. ... These results indicate that avian anti-TNF is quite effective at neutralizing the effects of TNF in this cell-based assay.

Thus, the Examiner is clearly wrong about what is taught in the specification. More importantly, the Examiner should not be permitted to ignore Applicants' distinction vis-à-vis Eibl II.

F. The Present Invention Is Not Obvious

When determining obviousness, sometimes the trick to invention is identifying "unmarked trees."

> It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail . . . to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees.

In re Ruschig, 379 F.2d 990, 994-95, 154 USPQ 118, 122 (CCPA 1967). Consistent with this analysis, Le et al. mentions numerous other indications but Le et al. does not mention NEC. The fact that necrotizing enterocolitis was not listed among a numerous list of possible indications suggests that Le et al. never considered treating necrotizing enterocolitis, thereby undermining the Examiner's obviousness argument.

The Applicants previously argued that the Examiner was making conclusory arguments without factual evidence and was substituting personal opinion for considered conclusions made by one having ordinary skill in the art. The Examiner has attempted to distinguish *In re Rijckaert* by stating that "... *In re Rijacert* is factually unrelated to the case at bar". *Examiner's*

Answer pg. 14 last two sentences. The Applicants remind the Board that all cases have different facts. The holdings of *In re Rijckaert* are not factually dependent, and is applicable in this matter.

The Examiner also misunderstands the holdings of another case, *In re Keller*. Many Examiners, including this one, believe that Applicants' properly structured obviousness argument discussing each and every reference cited by the Examiner amount to arguing the references individually:

> Accordingly, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller ...

Examiner's Answer, pg. 8. As the Board well knows, the holdings of *In re Keller* is directed to antiobviousness arguments that only discuss one of several cited references (i.e., the balance of the references are never even mentioned). That is not the case here.

Further, the Examiner has attempted to convince the Board that the Applicants have "... selectively relied on a typographical error to support his erroneous conclusion". *Examiner's Answer pg 16.* The Applicants have not relied upon any typographical error, and if the Examiner made a mistake in constructing the argument, it makes no difference in exposing this improper combination of references. Further, the Applicants submit that typos do not win cases.

We respectfully submit that by looking at the references themselves would not obviously lead one skilled in the art to create the Applicants' invention. Even if the Examiner has established a *prima facie* case of obviousness (which we do not agree), we have sufficiently rebutted by pointing out the weakness in the Examiners cited references as to what they teach, and considering the invention as whole, the invention as encompassed in the currently pending claims satisfies the requirements of 35 U.S.C. Section 103(a).

Respectfully submitted
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Dated: 2/8/2007

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